

REMARKS

Claims 61-80 are pending in the present application. Claims 71-80 have been withdrawn, in response to a restriction and election requirement. In view of the amendments to the pending Claims and these remarks, reconsideration of the rejections made in the Office Action is respectfully requested.

Claims 61-70 have been provisionally rejected under 35 U.S.C. 101 for statutory-type double patenting in view of co-pending U.S.S.N. 10/613,434. (It should be noted that a Preliminary Amendment was filed on the filing date of the co-pending U.S.S.N. 10/613,434, which resulted in only twenty claims remaining pending in that application.) The pending claims of the present application are not drawn to identical subject matter, and thus not co-extensive with pending claims of the co-pending application. Therefore the provisional double patenting rejection should be removed.

Claims 61-65 and 68-70 have been rejected under 35 U.S.C. 102(e)(2) as anticipated by Anderson, U.S. Pat. No. 6,456,942 ("Anderson '942"). Considering these remarks, and in view of the amendments to the claims, reconsideration is requested. Anderson '942 does not disclose or suggest the present invention, as set forth in Applicants claims.

At the outset, some of the distinguishing features and elements of the present invention and claims should be reiterated here. In pharmaceutical development, the procurement of highly relevant patient samples for genomic study is crucial. For research targeting specific disease or condition, researchers often must obtain specific samples of, for example, tissue or DNA, which will focus their study and achieve the intended development. Pharmaceutical target identification and target validation are critically dependant upon the availability and quality of research DNA and related samples. Extraordinary time, effort and expense often accompanies the screening of sample donors, collection of specimens, and most importantly the storage and archiving of such collected samples for later retrieval, for use in genomic study. Preservation of samples in, for example the livestock industry or veterinary research, for later selection and retrieval is another pervasive need. Prior to the present invention, typical sample procurement was limited to solicitation of frozen aliquots of liquid samples in the large freezers of multiple institutions in multiple locations. This often present the researcher with significant obstacles.

These are needs in the art to which the presently claimed invention is directed, as set forth for example at page 8, lines 13-20, pages 26-28, and Figures 1 and 2 of Applicants specification. By providing a researcher in a remote location the ability to conveniently search for and select in specific combination valuable samples according to disease or phenotype characteristics of the biological sample patient or source, and have use of specifically identified sample portions which have been preserved in dry format and archived, faster and improved pharmaceutical development and other studies may be achieved.

In contrast to the present invention, Anderson '942 describes and is directed to the synthesis of oligimers and the like, using electromechanical solid phase or photolithographic equipment. It is clear to one skilled in the art that artificial production of DNA-like molecules is not relevant to the screening and selection of actual disease characterized patient samples. In this sense, the polymers produced in the Anderson '942 method are not even "samples" as described in the present invention. Nowhere in the Anderson '942 patent is the collection or storage of actual patient samples even mentioned. The Anderson '942 patent does not in any way suggest or describe the selection of samples based upon source disease or phenotype, as presently claimed by Applicant. (see also, for example, Applicants specification at page 19, lines 17-19). These are substantial distinctions. The novelty of Applicant's invention as set forth in the claims having been made clear, the rejection under 35 U.S.C. 102(e)(2) should be removed.

Claims 61-70 have been further rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson '942 taken in view of Aryev et al. Pat. No. 6,581,012 (Aryev et al.). Reconsideration of this rejection is also respectfully requested.

As set forth above in response to the rejection under 35 U.S.C. 102, among other distinctions, the Anderson '942 patent does not teach or suggest the remote selecting of samples derived from biological sources and stored in dry state in a searchable archive. Moreover, the suggested combination with the Aryev et al. patent does not redirect nor complete any of the deficiencies of the Anderson patent.

The Aryev et al. patent describes a laboratory work flow system and software for the automation of traditional clinical testing of physical patient samples. Nowhere in the Aryev

et al. patent is a sample archive, particularly an archive of dry and stable samples, which samples are selectable via a catalog accessible from a remote location, even mentioned or suggested. The maintenance of lab results or medical insurance data in a database, as mentioned in Aryev et al. at Col. 3, lines 51-56, is in no way descriptive or suggestive of selection of samples based upon associated disease or phenotypic attributes of the biological source of the sample. In this regard, the mere business records associated with the hospital specimens in the Aryev et al. patent are quite distinct from the research repository documentation of disease and phenotype which are set forth in the specification and claims of the present application.

Moreover, one skilled in the art of genomic samples and pharmaceutical development would not look to Aryev et al. as being relevant. Automation of hospital and clinical sample testing is not at all the problem to be solved by the present invention. There is no suggestion at all in Aryev et al. of any database useful in selecting samples based upon their attributes. In fact, Aryev actually teaches away from the present invention, in that the tests to be conducted as part of the automation software methods described are both "predetermined", and performed or "ordered" only on mandated samples (see for example Col. 2, lines 54-58). There is no motivation to combine the teachings of the Aryev et al. patent with Anderson, as suggestive of a catalog of distinct archive samples, as set forth in the present claims.

To establish a *prima facie* case of obviousness, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references. The teachings or suggestions, as well as the second requirement, expectation of success, must come from the prior art, not applicants' disclosure. The proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. In other words, a hindsight analysis is never proper.

Applicants respectfully submit that the respective teachings of the Anderson '942 and Aryev et al. references represent only isolated disclosures with no suggestion or incentive therein that would have motivated those of ordinary skill to modify their respective disclosures and arrive at the invention set forth in the present claims. Nor was there any reasonable expectation that substituting the medical billing database of Aryev et al. into the


fairly construed disclosure of Anderson '942 would be at all successful in achieving the results set forth by Applicants invention.

Applicants respectfully submit that no motivation exists in the art to properly combine references in a meaningful manner. The desirable properties of the methods set forth in the present claims are unexpected results, and provide a useful improvement meeting the needs of the genomic and pharmaceutical research community.

For these reasons, it is respectfully stated that a *prima facie* case of obviousness has not been made, and accordingly the rejection under 35 U.S.C. 103 should be removed.

Applicants respectfully request the present application be moved to allowance. If the Examiner believes that a telephone conference with the undersigned would expedite passage of the present patent application to allowance and issue, they are cordially invited to call the undersigned at the number below.

Respectfully submitted,

By: 
Robert D. Touslee

Registration No. 34,032
Telephone: 303.933.0103
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